



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6356]

Investigational In Vitro Diagnostics Used in Clinical Investigations of Therapeutic Products;
Draft Guidance for Industry, Food and Drug Administration Staff, Sponsors, and Institutional
Review Boards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Investigational IVDs Used in Clinical Investigations of Therapeutic Products." This draft guidance is intended to assist sponsors of clinical investigations of therapeutic products that also include investigational in vitro diagnostics (IVDs) and institutional review boards (IRBs) that review such investigations in complying with the Investigational Device Exemption (IDE) regulation. This draft guidance is also intended to assist FDA staff participating in the review of these investigations. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-6356 for "Investigational IVDs Used in Clinical Investigations of Therapeutic Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Investigational IVDs Used in Clinical Investigations of Therapeutic Products" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: David Litwack, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4548, Silver Spring, MD 20993-0002, 301-796-6697 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to assist sponsors of clinical investigations of therapeutic products that also include investigational IVDs and IRBs that review such investigations in complying with the IDE regulation. This draft guidance is also intended to assist FDA staff participating in the review of these investigations.

This draft guidance describes when the IDE regulation may apply to certain clinical investigations of therapeutic products; certain regulatory requirements that sponsors should be aware of as they develop and conduct such investigations; recommendations for determining the risk of investigational IVD use in a therapeutic product investigation; recommendations for IRBs in reviewing such investigations; and recommendations for content to provide in an IDE application, when required.

Additionally, FDA is seeking feedback on the policy in the draft guidance regarding the need for an IDE for a significant risk study of an investigational IVD device with a therapeutic product under an IND. Specifically, FDA requests stakeholder perspectives on whether it would be beneficial to allow submission of all IDE components to an IND rather than require both an IDE and an IND. If such an approach would be beneficial, please identify any specific circumstances, for example a companion diagnostic and the associated therapeutic product, where efficiency may be improved or burden may be decreased, or both, without compromising patient safety.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's

current thinking on investigational IVDs used in clinical investigations of therapeutic products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This draft guidance is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Investigational IVDs Used in Clinical Investigations of Therapeutic Products” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400025 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 809 have been approved under OMB control number 0910-0485; the collections of information in parts 50 and 56 have been approved under OMB control number 0910-0755; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR 50.23 have been approved under OMB control number 0910-0586; the collections of information in 21 CFR part 812 have

been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in the guidance document entitled “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910-0756.

Dated: December 12, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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